

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendant
PFIZER INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

ANTOINETTE EMERSON, Individually, and on
Behalf of the Estate of WILLIE EMERSON,
Deceased,

Plaintiff,

vs.

PFIZER, INC.,

Defendant.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-01456-CRB

) **PFIZER INC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), ("Defendant"), and files this Answer to Plaintiff's Complaint
3 ("Complaint"), and would respectfully show the Court as follows:

4 **I.**

5 **PRELIMINARY STATEMENT**

6 The Complaint does not state in sufficient detail when Decedent was prescribed or used
7 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
8 Defendant may seek leave to amend this Answer when discovery reveals the specific time
9 periods in which Decedent was prescribed and used Bextra®.

10 **II.**

11 **ANSWER**

12 **Response to Allegations Regarding Parties**

13 1. Defendant admits that Plaintiff brought this civil action seeking monetary damages, but
14 denies that Plaintiff is entitled to any relief or damages. Defendant admits that, during certain
15 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendant admits that, during certain periods of
18 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
19 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
20 providers who are by law authorized to prescribe drugs in accordance with their approval by the
21 FDA. Defendant states that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant states that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage,
26 and denies the remaining allegations in this paragraph of the Complaint.

27 2. Defendant is without knowledge or information sufficient to form a belief as to the truth
28 of the allegations regarding Decedent's age and citizenship, and, therefore, denies the same.

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1 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
2 allegations regarding whether Decedent used Bextra® and Decedent's medical condition, and,
3 therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the
4 Complaint.

5 3. Defendant admits that Pfizer is a Delaware corporation with its principal place of
6 business in New York. Defendant admits that Pharmacia acquired Searle in 2000 and that, as
7 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
8 Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
9 Bextra® in the United States, including California, to be prescribed by healthcare providers
10 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
11 Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and
12 ambiguous. Defendant is without knowledge or information to form a belief as to the truth of
13 such allegations, and, therefore, denies the same. Defendant denies the remaining allegations in
14 this paragraph of the Complaint.

15 **Response to Allegations Regarding Jurisdiction and Venue**

16 4. Defendant is without knowledge or information to form a belief as to the truth of the
17 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
18 therefore, denies that the same. However, Defendant admits that Plaintiff claims that the
19 amount in controversy exceeds \$75,000, exclusive of interests and costs.

20 5. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the
22 amount in controversy, and, therefore, denies the same. However, Defendant admits that
23 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
24 exclusive of interests and costs.

25 6. Defendant is without knowledge or information sufficient to form a belief as to the truth
26 of the allegations in this paragraph of the Complaint regarding the judicial district in which the
27 asserted claims allegedly arose, and, therefore, denies the same. Defendant denies committing
28 a tort in the State of Arkansas or the State of California and denies the remaining allegations in

1 this paragraph of the Complaint.

2 7. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
 3 Bextra® in the United States, including California and Louisiana, to be prescribed by healthcare
 4 providers who are by law authorized to prescribe drugs in accordance with their approval by the
 5 FDA. Defendant admit that, during certain periods of time, Bextra® was manufactured and
 6 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra®
 7 in the United States to be prescribed by healthcare providers who are by law authorized to
 8 prescribe drugs in accordance with their approval by the FDA. Defendant admits that they
 9 provided FDA-approved prescribing information regarding Bextra®. Defendant admits that
 10 they do business in the State of California. Defendant states that Plaintiff's allegations
 11 regarding "predecessors in interest" are vague and ambiguous. Defendant is without
 12 knowledge or information to form a belief as to the truth of such allegations, and, therefore,
 13 denies the same. Defendant denies any wrongful conduct and denies the remaining allegations
 14 in this paragraph of the Complaint.

15 **Response to Allegations Regarding Interdistrict Assignment**

16 8. Defendant states that this paragraph of the Complaint contains legal contentions to
 17 which no response is required. To the extent that a response is deemed required, Defendant
 18 admits that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
 19 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
 20 Panel on Multidistrict Litigation on September 6, 2005.

21 **Response to Factual Allegations**

22 9. Defendant is without knowledge or information sufficient to form a belief as to the truth
 23 of the allegations regarding Decedent's medical condition and whether Decedent used Bextra®
 24 and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra®
 25 caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in this
 26 paragraph of the Complaint.

27 10. Defendant admits that Bextra® was expected to reach consumers without substantial
 28 change from the time of sale. Defendant is without knowledge or information sufficient to form

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1 a belief as to the truth of the allegations regarding whether Decedent used Bextra® and,
2 therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the
3 Complaint.

4 11. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
9 allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
10 Defendant denies the remaining allegations in this paragraph of the Complaint.

11 12. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as non-
12 steroidal anti-inflammatory drugs (“NSAIDS”). Defendant states that Bextra® was and is safe
13 and effective when used in accordance with its FDA-approved prescribing information.
14 Defendant states that the potential effects of Bextra® were and are adequately described in its
15 FDA-approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendant denies the remaining allegations in this
17 paragraph of the Complaint.

18 13. The allegations in this paragraph of the Complaint are not directed toward Defendant
19 and, therefore, no response is required. To the extent a response is deemed required, Defendant
20 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
21 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
22 to the truth of such allegations and, therefore, denies the same.

23 14. The allegations in this paragraph of the Complaint are not directed toward Defendant
24 and, therefore, no response is required. To the extent a response is deemed required, Defendant
25 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
26 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
27 to the truth of such allegations and, therefore, denies the same.

28 15. The allegations in this paragraph of the Complaint are not directed toward Defendant

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1 and, therefore, no response is required. To the extent a response is deemed required, Defendant
2 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
3 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
4 to the truth of such allegations and, therefore, denies the same.

5 16. The allegations in this paragraph of the Complaint are not directed toward Defendant
6 and, therefore, no response is required. To the extent a response is deemed required, Defendant
7 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
8 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
9 to the truth of such allegations and, therefore, denies the same.

10 17. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
11 Complaint. Defendant lacks sufficient information or knowledge to form a belief as to the truth
12 of such allegations and, therefore, denies the same.

13 18. Defendant states that Plaintiff's allegations regarding "predecessors in interest" are
14 vague and ambiguous. Defendant is without knowledge or information to form a belief as to
15 the truth of such allegations, and, therefore, denies the same. Defendant denies any wrongful
16 conduct and denies the remaining allegations in this paragraph of the Complaint.

17 19. Plaintiff does not allege that Decedent used Celebrex® in this Complaint. Nevertheless,
18 Defendant admits that Celebrex® was launched in the United States in February 1999.
19 Defendant states that Celebrex® was and is safe and effective when used in accordance with its
20 FDA-approved prescribing information. Defendant admits that, during certain periods of time,
21 Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
22 providers who are by law authorized to prescribe drugs in accordance with their approval by the
23 FDA. Defendant admits that, during certain periods of time, Celebrex® was manufactured and
24 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
25 Celebrex® in the United States to be prescribed by healthcare providers who are by law
26 authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in
27 this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward
28 Defendant and, therefore, no response is required. To the extent a response is deemed required,

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1 Defendant states that Plaintiff fails to provide the proper context for the allegations in this
2 paragraph of the Complaint regarding Merck and Vioxx®. Defendant therefore lacks sufficient
3 information or knowledge to form a belief as to the truth of such allegations and, therefore,
4 denies the same. Defendant denies the remaining allegations in this paragraph of the
5 Complaint.

6 20. Defendant admits that the New Drug Application for Bextra® was filed with the FDA
7 on January 15, 2001. Defendant admits, as indicated in the package insert approved by the
8 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
9 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant
10 states that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
11 Defendant is without knowledge or information to form a belief as to the truth of such
12 allegations, and, therefore, denies the same. Defendant denies the remaining allegations in this
13 paragraph of the Complaint.

14 21. Defendant admits that Bextra® was approved by the FDA on November 16, 2001.
15 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is
16 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
17 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
18 allegations in this paragraph of the Complaint.

19 22. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra®
20 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
21 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies
22 the remaining allegations in this paragraph of the Complaint.

23 23. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra®
24 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
25 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant states
26 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
27 prescribing information. Defendant states that the potential effects of Bextra® were and are
28 adequately described in its FDA-approved prescribing information, which at all times was

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adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

24. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendant is without knowledge or information to form a belief as to the truth of such allegations, and, therefore, denies the same. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

25. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct and denies the

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1 remaining allegations in this paragraph of the Complaint.

2 26. Defendant states that the referenced article speaks for itself and respectfully refers the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant denies the remaining allegations in
6 this paragraph of the Complaint.

7 27. The allegations in this paragraph of the Complaint are not directed towards Defendant
8 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
9 states that the referenced article speaks for itself and respectfully refers the Court to the article
10 for its actual language and text. Any attempt to characterize the article is denied. Defendant
11 denies the remaining allegations in this paragraph of the Complaint.

12 28. Defendant admits that the New Drug Application for Bextra® was filed with the FDA
13 on January 15, 2001. Defendant admits that Bextra® was approved by the FDA on November
14 16, 2001. Defendant denies any wrongful conduct and the remaining allegations in this
15 paragraph of the Complaint.

16 29. Defendant states that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendant states that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which at all times was adequate and comported with applicable standards of care and law.
20 Defendant denies the allegations in this paragraph of the Complaint.

21 30. Defendant states that the referenced FDA Talk Paper for Bextra® speaks for itself and
22 respectfully refers the Court to the Talk Paper for its actual language and text. Any attempt to
23 characterize the Talk Paper is denied. Defendant denies the remaining allegations in this
24 paragraph of the Complaint.

25 31. Defendant states that the referenced article speaks for itself and respectfully refers the
26 Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendant denies the remaining allegations in this paragraph of the Complaint.

28 32. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug

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1 approval meta-analysis study” in this paragraph of the Complaint. Defendant is without
2 sufficient information to confirm or denies such allegations and, therefore, denies the same.
3 Defendant states that the referenced study speaks for itself and respectfully refers the Court to
4 the study for its actual language and text. Any attempt to characterize the study is denied.
5 Defendant denies the remaining allegations in this paragraph of the Complaint.

6 33. The allegations in this paragraph of the Complaint are not directed towards Defendant
7 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
8 states that the referenced article speaks for itself and respectfully refers the Court to the article
9 for its actual language and text. Any attempt to characterize the article is denied. Defendant
10 denies the remaining allegations in this paragraph of the Complaint.

11 34. The allegations in this paragraph of the Complaint are not directed towards Defendant
12 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
13 admits that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk
14 Management Advisory Committee was held on February 16-18, 2005. Defendant states that the
15 referenced testimony speaks for itself and respectfully refers the Court to the testimony for its
16 actual language and text. Any attempt to characterize the testimony is denied. Defendant
17 denies the remaining allegations in this paragraph of the Complaint.

18 35. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant denies any wrongful conduct and
20 denies the remaining allegations in this paragraph of the Complaint.

21 36. Defendant states that the referenced Alert for Healthcare Professionals speaks for itself
22 and respectfully refers the Court to the Alert for Healthcare Professionals for its actual language
23 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
24 Defendant denies the remaining allegations in this paragraph of the Complaint.

25 37. Defendant states that the referenced Alert for Healthcare Professionals speaks for itself
26 and respectfully refers the Court to the Alert for Healthcare Professionals for its actual language
27 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
28 Defendant denies the remaining allegations in this paragraph of the Complaint.

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1 38. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant denies the allegations in this
3 paragraph of the Complaint.

4 39. Defendant states that the referenced article speaks for itself and respectfully refers the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendant denies any wrongful conduct and denies the remaining allegations in this
7 paragraph of the Complaint.

8 40. The allegations in this paragraph of the Complaint are not directed towards Defendant
9 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
10 states that the referenced article speaks for itself and respectfully refers the Court to the article
11 for its actual language and text. Any attempt to characterize the article is denied. Defendant
12 denies the remaining allegations in this paragraph of the Complaint.

13 41. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendant denies the allegations in this paragraph of the Complaint.

18 42. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
23 remaining allegations in this paragraph of the Complaint.

24 43. Defendant states that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendant states that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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1 of the Complaint.

2 44. Defendant denies the allegations in this paragraph of the Complaint.

3 45. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
4 Bextra® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
6 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
7 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
8 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
9 with their approval by the FDA. Defendant states that Bextra® was and is safe and effective
10 when used in accordance with its FDA-approved prescribing information. Defendant states that
11 the potential effects of Bextra® were and are adequately described in its FDA-approved
12 prescribing information, which was at all times adequate and comported with applicable
13 standards of care and law. Defendant is without knowledge or information sufficient to form a
14 belief as to the truth of the allegations regarding whether Decedent used Bextra® and,
15 therefore, denies the same. Defendant denies any wrongful conduct and denies the allegations
16 in this paragraph of the Complaint.

17 46. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
18 Bextra® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
20 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
21 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
22 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
23 with their approval by the FDA. Defendant states that Bextra® was and is safe and effective
24 when used in accordance with its FDA-approved prescribing information. Defendant states that
25 the potential effects of Bextra® were and are adequately described in its FDA-approved
26 prescribing information, which was at all times adequate and comported with applicable
27 standards of care and law. Defendant denies the remaining allegations in this paragraph of the
28 Complaint.

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1 47. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
2 Bextra® in the United States to be prescribed by healthcare providers who are by law
3 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
4 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
5 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
6 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
7 with their approval by the FDA. Defendant states that Bextra® was and is safe and effective
8 when used in accordance with its FDA-approved prescribing information. Defendant states that
9 the potential effects of Bextra® were and are adequately described in its FDA-approved
10 prescribing information, which was at all times adequate and comported with applicable
11 standards of care and law. Defendant admits, as indicated in the package insert approved by the
12 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
13 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant
14 denies the remaining allegations in this paragraph of the Complaint.

15 48. Defendant states that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which at all times was adequate and comported with applicable standards of care and law.
19 Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and
20 ambiguous. Defendant is without knowledge or information to form a belief as to the truth of
21 such allegations, and, therefore, denies the same. Defendant denies any wrongful conduct,
22 denies that Bextra® is defective, and denies the allegations in this paragraph of the Complaint.

23 49. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
24 Bextra® in the United States to be prescribed by healthcare providers who are by law
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
26 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
27 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
28 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

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1 with their approval by the FDA. Defendant states that Bextra® was and is safe and effective
2 when used in accordance with its FDA-approved prescribing information. Defendant states that
3 the potential effects of Bextra® were and are adequately described in its FDA-approved
4 prescribing information, which was at all times adequate and comported with applicable
5 standards of care and law. Defendant denies the remaining allegations in this paragraph of the
6 Complaint.

7 50. Defendant states that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which at all times was adequate and comported with applicable standards of care and law.
11 Defendant denies the remaining allegations in this paragraph of the Complaint.

12 51. Defendant states that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
17 of the Complaint.

18 52. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
23 of the Complaint.

24 53. Defendant denies the allegations in this paragraph of the Complaint.

25 54. Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market
26 as of April 7, 2005. Defendant denies any wrongful conduct and denies the remaining
27 allegations contained in this paragraph of the Complaint.

28 55. Defendant states that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendant states that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
5 remaining allegations in this paragraph of the Complaint.

6 56. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 57. Defendant denies any wrongful conduct and denies the remaining allegations in this
13 paragraph of the Complaint.

14 58. Defendant states that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendant states that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
19 Bextra® in the United States to be prescribed by healthcare providers who are by law
20 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
21 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
22 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
24 with their approval by the FDA. Defendant denies any wrongful conduct and denies the
25 remaining allegations in this paragraph of the Complaint.

26 59. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
27 Bextra® in the United States to be prescribed by healthcare providers who are by law
28 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits

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1 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
2 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
3 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
4 with their approval by the FDA. Defendant denies the remaining allegations in this paragraph
5 of the Complaint.

6 60. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
7 Bextra® in the United States to be prescribed by healthcare providers who are by law
8 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
9 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
10 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
11 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
12 with their approval by the FDA. Defendant admits, as indicated in the package insert approved
13 by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of
14 osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
15 dysmenorrhea. Defendant denies any wrongful conduct and denies the remaining allegations in
16 this paragraph of the Complaint.

17 61. Defendant states that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant states that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
22 allegations regarding and whether Decedent used Bextra® and, therefore, denies the same.
23 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
24 caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in this
25 paragraph of the Complaint.

26 62. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
3 allegations regarding and whether Decedent used Bextra® and, therefore, denies the same.
4 Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and
5 ambiguous. Defendant is without knowledge or information to form a belief as to the truth of
6 such allegations, and, therefore, denies the same. Defendant denies any wrongful conduct,
7 denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or
8 damage, and denies the remaining allegations in this paragraph of the Complaint.

9 **Response to First Cause of Action: Negligence**

10 63. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
11 Complaint as if fully set forth herein.

12 64. Defendant states that this paragraph of the Complaint contains legal contentions to
13 which no response is required. To the extent a response is deemed required, Defendant admits
14 that it had duties as are imposed by law but denies having breached such duties. Defendant
15 states that the potential effects of Bextra® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendant states that Bextra® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendant
19 denies the remaining allegations in this paragraph of the Complaint.

20 65. Defendant states that this paragraph of the Complaint contains legal contentions to
21 which no response is required. To the extent a response is deemed required, Defendant admits
22 that it had duties as are imposed by law but denies having breached such duties. Defendant
23 states that Bextra® was and is safe and effective when used in accordance with its FDA-
24 approved prescribing information. Defendant denies the remaining allegations in this paragraph
25 of the Complaint.

26 66. Defendant states that this paragraph of the Complaint contains legal contentions to
27 which no response is required. To the extent that a response is deemed required, Defendant
28 admits that it had duties as are imposed by law but denies having breached such duties.

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1 Defendant states that Bextra® was and is safe and effective when used in accordance with its
2 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
3 were and are adequately described in its FDA-approved prescribing information, which was at
4 all times adequate and comported with applicable standards of care and law. Defendant denies
5 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint,
6 including all subparts.

7 67. Defendant states that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
12 allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
13 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
14 of the Complaint.

15 68. Defendant states that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
20 of the Complaint.

21 69. Defendant states that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,
23 denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in
24 this paragraph of the Complaint.

25 70. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
26 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
27 Complaint.

28 71. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or

1 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
2 Complaint.

3 72. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
4 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
5 Complaint.

6 **Response to Second Cause of Action: Strict Liability**

7 73. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
8 Complaint as if fully set forth herein.

9 74. Defendant is without knowledge or information sufficient to form a belief as to the truth
10 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
11 Defendant admits that Bextra® was expected to reach consumers without substantial change in
12 the condition from the time of sale. Defendant admits that, during certain periods of time,
13 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
14 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
15 approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was
16 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
17 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
18 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
19 states that Bextra® was and is safe and effective when used in accordance with its FDA-
20 approved prescribing information. Defendant states that the potential effects of Bextra® were
21 and are adequately described in its FDA-approved prescribing information, which was at all
22 times adequate and comported with applicable standards of care and law. Defendant denies the
23 remaining allegations in this paragraph of the Complaint.

24 75. Defendant states that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendant states that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies the allegations in this paragraph of the Complaint.

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1 76. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant states that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendant denies that Bextra® is defective or unreasonably dangerous, and denies the
6 remaining allegations in this paragraph of the Complaint.

7 77. Defendant states that this paragraph of the Complaint contains legal contentions to
8 which no response is required. To the extent a response is deemed required, Defendant states
9 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
10 prescribing information. Defendant states that the potential effects of Bextra® were and are
11 adequately described in its FDA-approved prescribing information, which was at all times
12 adequate and comported with applicable standards of care and law. Defendant denies that
13 Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of
14 the Complaint, including all subparts.

15 78. Defendant states that this paragraph of the Complaint contains legal contentions to
16 which no response is deemed required. To the extent a response is deemed required, Defendant
17 states that Bextra® was and is safe and effective when used in accordance with its FDA-
18 approved prescribing information. Defendant states that the potential effects of Bextra® were
19 and are adequately described in its FDA-approved prescribing information, which was at all
20 times adequate and comported with applicable standards of care and law. Defendant denies any
21 wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining
22 allegations in this paragraph of the Complaint.

23 79. Defendant states that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
28 caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in this

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1 paragraph of the Complaint.

2 80. Defendant states that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendant states that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
7 remaining allegations in this paragraph of the Complaint.

8 81. Defendant is without knowledge or information sufficient to form a belief as to the truth
9 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
10 Defendant states that Bextra® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
12 were and are adequately described in its FDA-approved prescribing information, which was at
13 all times adequate and comported with applicable standards of care and law. Defendant admits
14 that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United
15 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
16 accordance with their approval by the FDA. Defendant admits that, during certain periods of
17 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
18 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
19 providers who are by law authorized to prescribe drugs in accordance with their approval by the
20 FDA. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that
21 Bextra® caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in
22 this paragraph of the Complaint.

23 82. Defendant states that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies the remaining allegations in this paragraph of the Complaint.

28 83. Defendant is without knowledge or information sufficient to form a belief as to the truth

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1 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
2 Defendant states that Bextra® was and is safe and effective when used in accordance with its
3 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
4 were and are adequately described in its FDA-approved prescribing information, which was at
5 all times adequate and comported with applicable standards of care and law. Defendant denies
6 the remaining allegations in this paragraph of the Complaint.

7 84. Defendant states that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendant denies any wrongful conduct and
9 denies the remaining allegations in this paragraph of the Complaint.

10 85. Defendant is without knowledge or information sufficient to form a belief as to the truth
11 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
12 Defendant states that Bextra® was and is safe and effective when used in accordance with its
13 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
14 were and are adequately described in its FDA-approved prescribing information, which was at
15 all times adequate and comported with applicable standards of care and law. Defendant denies
16 that Bextra® is defective and denies the remaining allegations in this paragraph of the
17 Complaint.

18 86. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
19 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
20 Complaint.

21 87. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
22 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
23 Complaint.

24 88. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
25 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
26 Complaint.

27 **Response to Third Cause of Action: Breach of Express Warranty**

28 89. Defendant incorporates by reference its responses to each paragraph of Plaintiff's

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1 Complaint as if fully set forth herein.

2 90. Defendant is without knowledge or information sufficient to form a belief as to the truth
3 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
4 Defendant states that Bextra® was and is safe and effective when used in accordance with its
5 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
6 were and are adequately described in its FDA-approved prescribing information, which was at
7 all times adequate and comported with applicable standards of care and law. Defendant admits
8 that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies
9 the remaining allegations in this paragraph of the Complaint.

10 91. Defendant is without knowledge or information sufficient to form a belief as to the truth
11 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
12 Defendant states that Bextra® was and is safe and effective when used in accordance with its
13 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
14 were and are adequately described in its FDA-approved prescribing information, which was at
15 all times adequate and comported with applicable standards of care and law. Defendant admits
16 that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies
17 the remaining allegations in this paragraph of the Complaint, including all subparts.

18 92. Defendant denies the allegations in this paragraph of the Complaint.

19 93. Defendant states that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendant states that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.
24 Defendant denies the remaining allegations in this paragraph of the Complaint.

25 94. Defendant states that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.
2 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
3 of the Complaint.

4 95. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
6 Defendant admit that it provided FDA-approved prescribing information regarding Bextra®.
7 Defendant denies the remaining allegations in this paragraph of the Complaint.

8 96. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
9 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
10 Complaint.

11 97. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
12 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
13 Complaint.

14 98. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
15 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
16 Complaint.

17 **Response to Fourth Cause of Action: Breach of Implied Warranty**

18 99. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
19 Complaint as if fully set forth herein.

20 100. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
21 Bextra® in the United States to be prescribed by healthcare providers who are by law
22 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
23 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
24 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
25 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
26 with their approval by the FDA. Defendant denies the remaining allegations in this paragraph
27 of the Complaint.

28 101. Defendant admits that it provided FDA-approved prescribing information regarding

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1 Bextra®. Defendant admits, as indicated in the package insert approved by the FDA, that
2 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
3 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant states
4 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
5 prescribing information. Defendant denies the remaining allegations in this paragraph of the
6 Complaint.

7 102. Defendant is without knowledge or information sufficient to form a belief as to the truth
8 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
9 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is
10 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
11 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
12 allegations in this paragraph of the Complaint.

13 103. Defendant is without knowledge or information sufficient to form a belief as to the truth
14 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
15 Defendant states that Bextra® was and is safe and effective when used in accordance with its
16 FDA-approved prescribing information. Defendant denies the remaining allegations in this
17 paragraph of the Complaint.

18 104. Defendant is without knowledge or information sufficient to form a belief as to the truth
19 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
20 Defendant states that Bextra® was expected to reach consumers without substantial change in
21 the condition from the time of sale. Defendant denies the remaining allegations in this
22 paragraph of the Complaint.

23 105. Defendant is without knowledge or information sufficient to form a belief as to the truth
24 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
25 Defendant states that Bextra® was and is safe and effective when used in accordance with its
26 FDA-approved prescribing information. Defendant denies any wrongful conduct and denies the
27 remaining allegations in this paragraph of the Complaint.

28 106. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or

1 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
2 Complaint.

3 107. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
4 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
5 Complaint.

6 108. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
7 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
8 Complaint.

9 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

10 109. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
11 Complaint as if fully set forth herein.

12 110. Defendant states that this paragraph of the Complaint contains legal contentions to
13 which no response is required. To the extent a response is deemed required, Defendant admits
14 that it had duties as are imposed by law but denies having breached such duties. Defendant
15 states that Bextra® was and is safe and effective when used in accordance with its FDA-
16 approved prescribing information. Defendant states that the potential effects of Bextra® were
17 and are adequately described in its FDA-approved prescribing information, which was at all
18 times adequate and comported with applicable standards of care and law. Defendant denies the
19 remaining allegations in this paragraph of the Complaint.

20 111. Defendant states that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
25 of the Complaint, including all subparts.

26 112. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
3 of the Complaint.

4 113. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably
9 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

10 114. Defendant states that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendant states that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
15 of the Complaint.

16 115. Defendant denies any wrongful conduct and denies the remaining allegations in this
17 paragraph of the Complaint.

18 116. Defendant is without knowledge or information sufficient to form a belief as to the truth
19 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
20 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
21 of the Complaint.

22 117. Defendant is without knowledge or information sufficient to form a belief as to the truth
23 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
24 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
25 of the Complaint.

26 118. Defendant is without knowledge or information sufficient to form a belief as to the truth
27 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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1 of the Complaint.

2 119. Defendant denies any wrongful conduct and denies the remaining allegations in this
3 paragraph of the Complaint.

4 120. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
6 Defendant states that Bextra® was and is safe and effective when used in accordance with its
7 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
8 were and are adequately described in its FDA-approved prescribing information, which was at
9 all times adequate and comported with applicable standards of care and law. Defendant denies
10 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

11 121. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
12 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
13 Complaint.

14 122. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
15 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
16 Complaint.

17 123. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
18 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
19 Complaint.

20 **Response to Sixth Cause of Action: Unjust Enrichment**

21 124. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
22 Complaint as if fully set forth herein.

23 125. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
24 Bextra® in the United States to be prescribed by healthcare providers who are by law
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
26 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
27 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
28 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

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1 with their approval by the FDA. Defendant denies the remaining allegations in this paragraph
2 of the Complaint.

3 126. Defendant is without knowledge or information sufficient to form a belief as to the truth
4 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
5 Defendant denies the remaining allegations in this paragraph of the Complaint.

6 127. Defendant is without knowledge or information sufficient to form a belief as to the truth
7 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
8 Defendant denies the remaining allegations in this paragraph of the Complaint.

9 128. Defendant is without knowledge or information sufficient to form a belief as to the truth
10 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
11 Defendant states that Bextra® was and is safe and effective when used in accordance with its
12 FDA-approved prescribing information. Defendant denies the remaining allegations in this
13 paragraph of the Complaint.

14 129. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
16 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent
17 injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

18 130. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or
19 Decedent injury or damage, and denies the remaining allegations in this paragraph of the
20 Complaint.

21 **Response to Seventh Cause of Action: Wrongful Death**

22 131. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
23 Complaint as if fully set forth herein.

24 132. Defendant is without knowledge or information sufficient to form a belief as to the truth
25 of the allegations regarding whether Decedent used Bextra® and, therefore, denies the same.
26 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent
27 injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

28 133. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or

Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

134. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

135. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

136. Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,” Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damage, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

III.

GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant’s labeling and warning of Bextra® was at all times in compliance with applicable

1 federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon
2 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
3 and violate the Supremacy Clause of the United States Constitution.

4 **Third Defense**

5 3. At all relevant times, Defendant provided proper warnings, information and instructions
6 for the drug in accordance with generally recognized and prevailing standards in existence at
7 the time.

8 **Fourth Defense**

9 4. At all relevant times, Defendant's warnings and instructions with respect to the use of
10 Bextra® conformed to the generally recognized, reasonably available, and reliable state of
11 knowledge at the time the drug was manufactured, marketed and distributed.

12 **Fifth Defense**

13 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
14 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

15 **Sixth Defense**

16 6. Plaintiff's action is barred by the statute of repose.

17 **Seventh Defense**

18 7. If Plaintiff or Decedent sustained any injuries or incurred any losses or damages as
19 alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and
20 Decedent and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative
21 fault and contributory negligence and by the failure to mitigate damages.

22 **Eighth Defense**

23 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
24 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part
25 of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable
26 in any way.

27 **Ninth Defense**

28 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,

1 intervening causes for which Defendant cannot be liable.

2 **Tenth Defense**

3 10. Any injuries or expenses incurred by Plaintiff and Decedent were not caused by
4 Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction,
5 operation of nature, or act of God.

6 **Eleventh Defense**

7 11. Defendant affirmatively denies that it violated any duty owed to Plaintiff or Decedent.

8 **Twelfth Defense**

9 12. A manufacturer has no duty to warn patients or the general public of any risk,
10 contraindication, or adverse effect associated with the use of a prescription medical product.
11 Rather, the law requires that all such warnings and appropriate information be given to the
12 prescribing physician and the medical profession, which act as a “learned intermediary” in
13 determining the use of the product. Bextra® is a prescription medical product, available only
14 on the order of a licensed physician. Bextra® provided an adequate warning to Decedent’s
15 treating and prescribing physicians.

16 **Thirteenth Defense**

17 13. The product at issue was not in a defective condition or unreasonably dangerous at the
18 time it left the control of the manufacturer or seller.

19 **Fourteenth Defense**

20 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit
21 for its intended use and the warnings and instructions accompanying Bextra® at the time of the
22 occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

23 **Fifteenth Defense**

24 15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the
25 Bextra® allegedly ingested by Decedent was prepared in accordance with the applicable
26 standard of care.

27 **Sixteenth Defense**

28 16. If Plaintiff or Decedent sustained any injuries or incurred any losses or damages as

1 alleged in the Complaint, the same were caused by the unforeseeable alteration, change,
2 improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other
3 than Defendant or persons acting on its behalf after the product left the control of Defendant.

4 **Seventeenth Defense**

5 17. Plaintiff's and Defendant's alleged damages were not caused by any failure to warn on
6 the part of Defendant.

7 **Eighteenth Defense**

8 18. Plaintiff's and Defendant's alleged injuries/damages, if any, were the result of
9 preexisting or subsequent conditions unrelated to Bextra®.

10 **Nineteenth Defense**

11 19. Plaintiff and Decedent knew or should have known of any risk associated with Bextra®;
12 therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

13 **Twentieth Defense**

14 20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are
15 preempted in accordance with the Supremacy Clause of the United States Constitution and by
16 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

17 **Twenty-first Defense**

18 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
19 the subject pharmaceutical product at issue was subject to and received pre-market approval by
20 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

21 **Twenty-second Defense**

22 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
23 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
24 and Plaintiff's causes of action are preempted.

25 **Twenty-third Defense**

26 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
27 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
28 issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitution of the State of Arkansas, and the Constitution of the State of California, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiff and Decedent failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Arkansas and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,

1 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
2 the time of the sale.

3 **Forty-first Defense**

4 41. If Plaintiff and Decedent have sustained injuries or losses as alleged in the Complaint,
5 upon information and belief, such injuries and losses were caused by the actions of persons not
6 having real or apparent authority to take said actions on behalf of Defendant and over whom
7 Defendant had no control and for whom Defendant may not be held accountable.

8 **Forty-second Defense**

9 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
10 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
11 intended, and was distributed with adequate and sufficient warnings.

12 **Forty-third Defense**

13 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
14 waiver, and/or estoppel.

15 **Forty-fourth Defense**

16 44. Plaintiff's claims are barred because Plaintiff's and Decedent's injuries, if any, were the
17 result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions,
18 diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff
19 and Decedent, and were independent of or far removed from Defendant's conduct.

20 **Forty-fifth Defense**

21 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
22 did not proximately cause injuries or damages to Plaintiff or Decedent.

23 **Forty-sixth Defense**

24 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff
25 and Decedent did not incur any ascertainable loss as a result of Defendant's conduct.

26 **Forty-seventh Defense**

27 47. The claims asserted in the Complaint are barred, in whole or in part, because the
28 manufacturing, labeling, packaging, and any advertising of the product complied with the

1 applicable codes, standards and regulations established, adopted, promulgated or approved by
 2 any applicable regulatory body, including but not limited to the United States, any state, and
 3 any agency thereof.

4 **Forty-eighth Defense**

5 48. The claims must be dismissed because Decedent would have taken Bextra® even if the
 6 product labeling contained the information that Plaintiff contends should have been provided.

7 **Forty-ninth Defense**

8 49. The claims asserted in the Complaint are barred because the utility of Bextra®
 9 outweighed its risks.

10 **Fiftieth Defense**

11 50. Plaintiff's damages, if any, are barred or limited by the payments received from
 12 collateral sources.

13 **Fifty-first Defense**

14 51. Defendant's liability, if any, can only be determined after the percentages of
 15 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
 16 any, are determined. Defendant seeks an adjudication of the percentage of fault of the
 17 claimants and each and every other person whose fault could have contributed to the alleged
 18 injuries and damages, if any, of Plaintiff.

19 **Fifty-second Defense**

20 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
 21 common law gives deference to discretionary actions by the United States Food and Drug
 22 Administration under the Federal Food, Drug, and Cosmetic Act.

23 **Fifty-third Defense**

24 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is
 25 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
 26 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
 27 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
 28 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,

1 and with the specific determinations by FDA specifying the language that should be used in the
2 labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the
3 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
4 United States.

5 **Fifty-fourth Defense**

6 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
7 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

8 **Fifty-fifth Defense**

9 55. Defendant states on information and belief that the Complaint and each purported cause
10 of action contained therein is barred by the statutes of limitations contained in California Code
11 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as
12 may apply.

13 **Fifty-sixth Defense**

14 56. Defendant states on information and belief that any injuries, losses, or damages suffered
15 by Plaintiff and Decedent were proximately caused, in whole or in part, by the negligence or
16 other actionable conduct of persons or entities other than Defendant. Therefore, Plaintiff's
17 recovery against Defendant, if any, should be reduced pursuant to California Civil Code §
18 1431.2.

19 **Fifty-seventh Defense**

20 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
21 Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil
22 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
23 damages is also barred under California Civil Code § 3294(b).

24 **Fifty-eighth Defense**

25 58. Any claims for breach of warranty are barred for lack of reasonable reliance, lack of
26 timely notice, lack of privity, and because the alleged warranties were excluded and/or
27 disclaimed.

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Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Fifty-ninth Defense

59. Plaintiff's claims are barred and/or limited by the provisions of the Arkansas Products Liability Act, Ark. Code Ann. § 16-116-101, et seq.

Sixtieth Defense

60. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Arkansas Civil Justice Reform Act of 2003, Ark. Code Ann. § 16-55-201 et seq.

Sixty-first Defense

61. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiff take nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendant be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's and Decedent's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendant in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's and Decedent's injuries and damages; and
6. That Defendant have such other and further relief as the Court deems appropriate.

1 April 24, 2008

GORDON & REES LLP

2
3 By: : _____/s/_____

4 Stuart M. Gordon
5 sgordon@gordonrees.com
6 Embarcadero Center West
7 275 Battery Street, 20th Floor
8 San Francisco, CA 94111
9 Telephone: (415) 986-5900
10 Fax: (415) 986-8054

11 April 24, 2008

TUCKER ELLIS & WEST LLP

12 By: : _____/s/_____

13 Michael C. Zellers
14 michael.zellers@tuckerellis.com
15 515 South Flower Street, Suite 4200
16 Los Angeles, CA 90071-2223
17 Telephone: (213) 430-3400
18 Fax: (213) 430-3409

19 Attorneys for Defendant
20 PFIZER INC.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

April 23, 2008

GORDON & REES LLP

By: : _____/s/_____

Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

April 24, 2008

TUCKER ELLIS & WEST LLP

By: : _____/s/_____

Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendant
PFIZER INC.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111